



CASE LA23b CIP-1

CERTIFICATE OF MAILING

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John M. Kilcoyne
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John M. Kilcoyne
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September 26, 2001
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1615

TIMMINS ET AL.

Examiner: P. Kulkosky

APPLICATION NO: 09/398,107

FILED: SEPTEMBER 16, 1999

FOR: BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM FOR
HIGH SOLUBILITY PHARMACEUTICALS AND METHOD

TECH CENTER 1600/2900

OCT 03 2001

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Assistant Commissioner for Patents
Washington, D.C. 20231

AMENDMENT

Sir:

In response to the Official Action mailed on March 26, 2001, please amend this application as follows:

In the specification:

Please replace the first paragraph on page 42 as follows:

A1 -- Metformin hydrochloride (502.5g) was mixed with sodium carboxymethylcellulose (Blanose 7HF) (50g) for five minutes in a small planetary mixer and sufficient purified water added with continued mixing to produce a damp granular mass. The wet granulation was dried at 60°C for 1 hour and then size reduced in a hammer mill. The granulation was dry blended with a mixture prepared from 358g of hydroxypropylmethylcellulose 2208 USP (100,000 cps grade), 10g of hydroxypropylmethylcellulose 2910 USP (5 cps grade) and 102g of microcrystalline cellulose in a planetary mixer for 10 minutes. Finally this mix was lubricated by mixing with 1% w/w magnesium stearate and compressed into capsule shaped tablets, each containing 0.5g of metformin hydrochloride. When tested for in vitro release of metformin the following results were obtained.

In the claims:

Please cancel claims 3, 16, 17, 25, 42, 50 and 71 without prejudice.

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A.